Testimony
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The HHS Pandemic Influenza Plan

Statement of

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Good morning, Mr. Chairman, Representative Dingell, and Members of the Committee. I am honored to be here today to present the President's request for funds for the HHS Pandemic Influenza Plan, which is an integral component of the National Strategy for Pandemic Influenza, which the President announced last week. In the event that an outbreak of pandemic flu hits our shores, it will surely have profound impacts on almost every sector of our society. Such an outbreak will require a coordinated response at all levels of government – Federal, State, and local – and it will require the participation of the private sector and each of us as individuals. HHS has been a leader in this effort. With this budget request and the release of the HHS Pandemic Influenza Plan, we are taking another major step forward to improve our preparedness and response capabilities.

The threat of an outbreak of pandemic influenza is real. An influenza virus strain with potential to cause a pandemic of human disease could emerge with little or no warning and in almost any part of the world, as occurred 3 times during the 20th century. Influenza viruses infect birds, pigs, and other animals, as well as humans. The ability of these viruses to cross the species barrier from time to time creates the possibility for the appearance of new viral strains that have the potential to be highly infectious, readily transmissible, and highly lethal. If a pandemic virus strain emerges, it is estimated that upwards of 30 percent of people exposed could become infected and the death rate will likely be considerably higher than that seen with seasonal influenza. Faced with such a threat, the United States and its international partners will need to respond quickly and efficiently to reduce the scope and magnitude of this serious health threat.

Today's threat is the H5N1 avian influenza strain, which is spreading widely and rapidly in domestic and migratory fowl in Asia and now in Eastern Europe. While the virus has not demonstrated the ability to spread efficiently from person to person, it has infected more than one hundred people in Asia and approximately 50 percent of these known cases have died. The virus is now endemic in many bird species and in several countries, so elimination is not feasible. The feared pandemic could become a reality if this virus mutates further, remains highly virulent, and acquires the capability to spread as efficiently from person to person as do the commonly circulating virus strains that produce seasonal influenza epidemics. But even if H5N1 does not lead to a pandemic, the likelihood of an influenza pandemic at some point remains high. This is why we need to prepare now in order to swiftly and efficiently respond to an outbreak.

We are taking important steps forward. Last week, I released the HHS Pandemic Influenza Plan, which is a blueprint for pandemic influenza preparation and response. The HHS Plan provides guidance to national, State, and local policy makers and health departments. The goal is for all involved to achieve a state of readiness and quick response.

The HHS Plan includes an overview of the threat of pandemic influenza, a description of the relationship of this document to other Federal plans and an outline of key roles and responsibilities during a pandemic. In addition, the HHS Plan specifies needs and opportunities to build robust preparedness for and response to pandemic influenza. The preparations made for a pandemic today will have lasting benefits for the future.

A pandemic outbreak will allow very little time to develop new capabilities or build surge capacity for response if these efforts are not already in place. Unfortunately, current capacity for domestic manufacture of influenza vaccine and antiviral drugs can meet only a small fraction of the need projected for a pandemic response. If we are to have the capabilities and capacities needed when a pandemic emerges, the investments to bring them about must be made now. That is why the President is requesting additional FY 2006 appropriations for HHS totaling $6.7 billion for the HHS Pandemic Influenza Plan. Our goals in seeking this funding are to be able to produce a course of pandemic influenza vaccine for every American within six months of an outbreak; provide enough antiviral drugs and other medical supplies to treat over 25 percent of the U.S. population; and ensure a domestic and international public health capacity to respond to a pandemic influenza outbreak.

First, we must establish the domestic vaccine production capacity our Nation will need to protect all Americans within six months of detection of a virus that begins to spread efficiently from human to human. In anticipation of an influenza pandemic, we must stockpile in advance sufficient quantities of pre-pandemic vaccine that is protective against circulating influenza virus strains with pandemic potential in order to be in a position to initiate vaccination of health care workers and front-line workers critical to the pandemic response. These pre-pandemic vaccine stockpiles must be regularly reevaluated and potentially replenished as the pandemic virus threat mutates and changes, and as vaccine potency degrades over time. In addition, as the virus strains evolve and

potentially escape protection by the existing vaccines, newer vaccines that better match the current pandemic strain will need to be produced and stockpiled. The Nation must also expand its stocks of antivirals, personal protective equipment (masks, gloves, etc.) and other supplies to help provide a potentially over-burdened healthcare system with the means to treat and care for those who become seriously ill in an influenza pandemic.

Second, we must enhance the disease surveillance systems both internationally and domestically and train the personnel needed to reliably detect an outbreak quickly and to accurately determine its lethality and transmissibility. This includes obtaining samples of the virus from infected humans and animals and having laboratory capacity, personnel, and supplies necessary to conduct rapid analysis. Surveillance is our early warning system, and faster detection will enable public health officials to make recommendations about containment protocols, such as limits on travel and the assembly of large groups of people. Faster detection and identification of emerging influenza virus strains facilitate the conversion by industry to mass production of pandemic influenza vaccines. Better State, Federal, and international diagnostic laboratory systems will also allow for increased surge capacity needed to support front-line medical personnel, and effectively guide the use of scarce drugs, vaccines, and other resources.

Improved surveillance systems, including near real-time collection of data from hospital emergency departments in major metropolitan areas through BioSense, will allow us to continuously track the spread of the virus and the morbidity/mortality it produces and to evaluate the effectiveness or our intervention strategies. This information will be critical

to determining the best uses of limited supplies of pandemic influenza countermeasures. We will also track vaccines and immunizations to ensure that we maximize its equitable use as well as its effectiveness and safety.

Third, we must develop in advance domestic and international plans for broad public education efforts that are culturally appropriate and provide critical information in ways that acknowledge different levels of health literacy. These efforts before and during a pandemic will help guide individual actions to prevent and reduce infection and clarify the need for prioritization of scarce vaccines and antivirals and other materials. Our request also includes funding for States and local municipalities to develop and/or update their pandemic influenza response plans and to integrate them with Federal plans.

INFLUENZA VACCINE

The Administration has been aggressively working to be able to acquire, over a two-year period, enough H5N1 vaccine and antivirals to protect 20 million people should they become infected with the pandemic virus. On July 15, 2005, the Administration submitted an FY 2006 Budget Amendment totaling $150 million to implement our "20/20" plan. This strategy was designed to give us considerable experience with commercial-scale manufacturing of this new vaccine, and provide some pre-pandemic vaccine to our stockpile. However, as we are only able to obtain pre-pandemic vaccine during the few months of the year when influenza vaccine manufacturers are not running at full capacity making the seasonal trivalent vaccine, we are severely limited in the quantity of vaccine that we can stockpile. In addition to this limitation, since the

submission of this Budget Amendment, we received results of H5N1vaccine clinical trials funded by NIH. As part of this strategy, the NIH has funded clinical trials of H5N1 influenza vaccine—which provided good news and, at the same time, sobering news. The good news was that the vaccine we developed works – it provides a good immune response that augurs well for protecting people against the H5N1 virus. The sobering news was that to achieve the desired immune response, the vaccine needed to be six times as potent as the seasonal vaccine -- 90 micrograms of the hemagluttinin component instead of 15 micrograms -- and that two doses are needed for the protective immune response. This has further driven home a point of which we were all aware—that the nation's capacity to produce enough 90-microgram doses of pandemic vaccine was woefully inadequate. We need an aggressive strategy to achieve the needed domestic vaccine manufacturing capacity as quickly as possible, and to initiate similarly aggressive action to implement other immediate preparedness strategies beyond these critical vaccine needs. This budget request is just such a strategy, building on the July Budget Amendment and responding aggressively to the results of the NIH clinical trials and our growing concern that a pandemic could involve hundreds of communities across the United States and around the world.

Of this week's $6.7 billion funding request, approximately $4.7 billion would go toward investments in creating pandemic influenza vaccine production capacity and stockpiles that will ensure that enough vaccine will be available to every American in the event of a flu pandemic. To accomplish this, HHS will pursue a multi-faceted strategy to create, as soon as possible, domestic influenza vaccine manufacturing capacity aimed at producing

300 million courses (two doses of vaccine per person) within six months of the onset of an influenza pandemic. With this immediate investment, the increased production capacity and related stockpile expansion will be achieved in phases between 2008 and 2013.

The initial component of this strategy is to expand the number of licensed domestic egg-based influenza vaccine manufacturers from the single one that currently exists. This would give the U.S. the ability to develop a 20 million course (40 million doses) pre-pandemic vaccine stockpile by 2009 – without disrupting the production of annual seasonal influenza vaccine. In the event of a pandemic outbreak, or perhaps before, the vaccine stockpile would be used to immunize healthcare workers, front-line responders, vaccine manufacturing personnel, and others critical to the pandemic response. Once this capacity is developed, current egg-based production techniques could then provide about 60 million courses of vaccine within six months of an outbreak, or about 20 percent of our goal of 300 million courses within six months.

The ultimate surge capacity goal of 300 million courses of vaccine cannot be achieved from egg-based production alone. Our best hope for creating capacity in the U.S. for rapidly ramping up vaccine production at any point in time is expansion and acceleration of our investment in cell-based influenza vaccines—and much of our planned investment goes toward this initiative. While promising, success of cell-based influenza vaccine production and licensure is still years off, and not a guarantee. Therefore, our vaccine capacity expansion strategy invests in both cell-based vaccines and the traditional, tried

and true egg-based vaccines. Therefore, HHS, in collaboration with the vaccine industry and its academic partners, will invest in the advanced development of cell-based techniques for manufacturing pandemic influenza vaccines. By financing the establishment of new cell-based vaccine manufacturing facilities that could open in 2010, our plan will develop the surge capacity needed to provide for the remaining ~80 percent (approximately 240 million courses) of the population within six months of a pandemic outbreak.

The HHS Pandemic Influenza Plan also acknowledges that existing manufacturing facilities can be directed to this effort and finances the retrofitting of existing domestic manufacturing facilities that would enable them to convert to production of pandemic influenza vaccine production, in an emergency. HHS will establish contingency arrangements with vaccine manufacturers in conjunction with the Food and Drug Administration so that, at the onset of an influenza pandemic, they will be able to readily adapt their facilities either to produce influenza vaccines or to provide a critical function, such as fill and finish bulk vaccine produced by other manufacturers.

We will also work with industry and academia to support advanced development of dose-stretching technologies, such as the use of adjuvants and new vaccine delivery systems. These investments, if successful, will extend the pandemic influenza vaccine supply and allow more Americans to receive pandemic vaccines sooner. We will also invest in research that may have potential to lead to broad-spectrum vaccines to protect against

multiple and emerging strains of influenza viruses. This would allow for stockpiling of vaccines that could be useful even as the virus strains evolve and change.

However, as we seek to build domestic manufacturing capacity, we also know that the threat of liability exposure is too often a barrier to willingness to participate in the vaccine business. As we recognize the desperate need to create and expand vaccine manufacturing capacity, we have to remove such deterrents to participation by those with the knowledge and experience to accomplish this. It is crucial that those engaged in this work be shielded from unwarranted tort suits. Accordingly, the Administration is proposing limited liability protections for vaccine manufacturers and providers, with an exception to allow suits to proceed against companies who act with willful misconduct. We believe this proposal strikes an appropriate balance of removing the liability risks that dissuade companies from producing pandemic countermeasures, while still retaining appropriate access to court remedies.

ANTIVIRALS

We also recognize the importance of having available a sufficient supply of stockpiled antiviral drugs to treat and care for infected individuals. For this, we request an investment of $1.4 billion. These funds would help us achieve the national goal of having available 81 million courses of antivirals, which would be sufficient to treat 25 percent of the U.S. population (75 million courses) and a reserve supply (6 million courses) that could be used to contain an initial U.S. outbreak. Funding would also be used to accelerate development of promising new antiviral drug candidates in

collaboration with academia and industry, since none of the antivirals today are likely to work perfectly against pandemic influenza.

Of the 81 million courses, six million courses will be designated to contain the first isolated domestic outbreaks. Of the 75 million courses that will be used to treat those who are infected with the pandemic virus, HHS would fully fund the procurement of 44 million treatment courses to provide protection to the highest priority groups in the event of an influenza pandemic. We will also work with our State partners to encourage them to acquire antivirals for rapid use for their populations. To help support these States efforts, we would establish contractual arrangements with manufacturers of approved antivirals whereby States may purchase up to 31 million treatment courses and HHS would pay for approximately 25 percent of the costs of these drugs. This arrangement will also ensure a more coordinated inter-governmental approach in the acquisition of antiviral drugs and pre-deployment stockpiles of antivirals around the nation. A guaranteed acquisition of up to 81 million courses of antiviral drugs will enable manufacturers to make significant expansion in its U.S.-based manufacturing capacity—thereby positioning itself to meet future demands much more readily than currently is possible.

I have personally been meeting with leaders of relevant vaccine manufacturers to determine how they might participate in preparedness for and response to a pandemic. To facilitate the development of new antivirals, HHS will collaborate with industrial

organizations to develop, obtain approval, and establish commercial production of new antivirals that would help protect the citizens of our Nation.

DISEASE SURVEILLANCE, PUBLIC HEALTH INFRASTRUCTURE, AND RISK COMMUNICATION

In addition to the production and stockpiling of vaccines and antivirals, enhancing domestic and international resources to expand surveillance, strengthening public health infrastructure, and effectively communicating with the public about risks of an influenza pandemic are important components of the HHS Pandemic Influenza Plan, for which we are requesting $555 million. A critical step in enhancing public health infrastructure and international collaboration will be to implement and refine surveillance and epidemiological response. These investments will help us detect, investigate, and respond to the onset of a potential influenza pandemic anywhere in the world without delay. Because influenza characteristically spreads beyond country boundaries, we have included in our request funding to be used internationally. These funds will follow the evolution of the virus in Asia, detect human cases, and help contain outbreaks, where feasible.

With an enhanced domestic and international early warning system, we will be better positioned to mount an immediate emergency response to characterize the outbreak; obtain viral samples for analysis and possible vaccine production; and we will have a greater chance to prevent, contain, and/or retard the spread of infection. The ability to continually analyze data to help predict the further course of the pandemic will help guide

the choice and timing of interventions (drugs, vaccine, and public health measures) and will help assess the efficacy of these interventions.

Enhancing our public health infrastructure also includes expanding the science base at the Food and Drug Administration, thus allowing for expedited regulatory review of pharmaceutical industry initiatives to develop the necessary new vaccine technologies, as well as speeding the licensure of the facilities and vaccines produced within them.

Risk communication is another integral part of an effective public health response plan. We must have in place the capability to employ effective risk communication practices that will guide us in providing the American people with the accurate, timely and credible information they will need to protect themselves and help others during an influenza pandemic. To ensure that our communications efforts resonate with target audiences, we will solicit the public's active participation and involvement in our efforts to develop relevant, easy-to-understand information and materials regarding influenza in general, and pandemic influenza in particular. To help in this effort, we have established a website devoted exclusively to this topic, pandemicflu.gov.

Public participation and involvement may include engaging the public in discussions on State and local community preparedness; assisting communities in developing procedures for disseminating information and guidance for all segments of our diverse population; and developing targeted informational tool-kits for distribution to particular stakeholders such as educators, physicians, and employers.

STATE AND LOCAL PARTNERS

Pandemic planning needs to incorporate every department of the Federal government but must also go deeper than that. Every State and local government must have a pandemic plan. Unlike most disasters, a pandemic outbreak can happen in hundreds or thousands of places simultaneously. The Federal government will play an important role, but engaged state and local partners are necessary for our success. Over the coming days, I will be asking the governors, mayors and State and local health and preparedness officials to join me in a concern we all must share -- preparing for a pandemic should one happen. Everyone in society has a role.

For example, the Federal government can deliver stockpiles of medication and supplies to a city in the U.S. in a matter of hours – but it is distribution at the State and local level that defines victory. In a moment of crisis, if we are not able to deliver pills to people over wide areas in short time frames, lives will be lost. We need to create a seamless preparedness network where we are all working together for the benefit of the American people. Of the $555 million for surveillance and public health infrastructure, our Budget request includes $100 million specifically for State and local pandemic preparedness efforts. And, as mentioned previously, we will provide incentives to States to purchase their own stocks of antivirals by allowing them to buy off of HHS-negotiated contracts and subsidizing about 25% of the cost.

The plan and budget request outlined above will greatly improve our short and long term preparedness posture. We are well-positioned to implement the plan and invest these new resources wisely and effectively only because of the substantial pandemic influenza activities already underway at HHS. Scientists at the National Institutes of Health and the Food and Drug Administration, working with industry, have developed a vaccine that produces an immune response sufficient to provide protection from the H5N1 virus. This bodes well for our ability to develop a vaccine against a pandemic virus that may evolve from the current H5N1 strain. In September, HHS awarded a $100 million contract to manufacture 3.3 million doses of H5N1 vaccine, which at two doses per person would be enough for 1.67 million people. In addition, just last week we announced the award of a $62.5 million contract to produce even more vaccine. We have also initiated contracts to secure an adequate supply of specialized eggs to initiate surge production at any time of year.

This is not a new undertaking. We are making progress, and with your help will continue to do so. We realize we are asking for significant funding at a time when the Administration and Congress are trying to control spending and reduce the deficit. We have controls in place at the Department, and within the structure of the funding request, to ensure that these funds are used wisely and responsibly. We acknowledge that investing in this plan without perfect knowledge of the future is expensive, and not without risk. However, waiting until a pandemic begins would be much more expensive in terms of American lives and economic impact. In our view, waiting is not an option.

I look forward to answering your questions, and more importantly, to working closely with you as we move forward together to protect our citizens.